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AN IMPLANT FOR AN OSTEOSYNTHESIS DEVICE, IN PARTICULAR FOR THE SPINE

TECHNICAL FIELD

5 The present invention relates to the technical field of osteosynthesis, in particular of the spine, and more precisely it relates to an implant comprising anchor screws in the vertebrae, designed to make it possible to position angularly a bracing rod extending along said vertebrae for the purpose of holding them stationary during a period of bone fusion.

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PRIOR ART

Various systems have been developed for correcting and stabilizing the spine and for facilitating bone fusion at various levels of the spine. In one such system, a rod is placed along the spine and is held in position by screws implanted in the vertebrae. The rod is suitable for being curved so as to follow the curvature of the region of the spine to which it is fitted. Thus, in order to comply with the anatomical shape of the spine, the bracing rod needs to be shaped so as to present considerable amounts of curvature, particularly in order to enable it to be installed relative to the lumbar and sacral vertebrae.

20 In order to make it possible for the rod to be shaped in this way while also ensuring that it is secured effectively to its anchor screws, proposals have been made to fit anchor screws with respective ball joints for receiving the bracing rod, so as to accommodate shape-following relative angles between the bracing rod and the anchor screws.

25 Thus, by way of example, European patent No. EP 0 614 649 describes an implant for an osteosynthesis device comprising a fixing body shaped in the form of a socket in which a reception channel is formed to receive a bracing rod. The fixing body is arranged to present a reception housing for the head of an anchor screw in order to define a ball joint between the anchor screw and the fixing body. That
30 implant also has a positioning ring for placing between the head of the anchor screw and the bracing rod. The implant also has a nut type system for assembling the bracing rod to the fixing body. Such a system has a nut screwed onto the outside walls of the fixing body and a threaded lock screw is screwed into the inside of the fixing body. By screwing such an assembly device tight it is possible to clamp firstly
35 the bracing rod between the lock screw and the positioning ring, and secondly the anchor screw between the positioning ring and the fixing body.

It must be considered that such an implant is made up of a plurality of parts that need to be built up into intermediate assemblies while the operation is taking place. This gives rise to difficulties of assembly and to installation time that is relatively lengthy.

5 Document DE 44 25 357 also describes an implant for an osteosynthesis device comprising a first assembly, itself comprising a fixing body arranged to present a reception housing for receiving the head of an anchor screw in order to define a ball joint between the anchor screw and the fixing body. This first assembly also has a positioning ring for interposing between the head of the anchor screw and
10 the bracing rod. That implant further comprises a second assembly, itself comprising a system of the nut type for assembling the bracing rod to the fixing body. Such an implant does not enable effective connection to be ensured between the anchor screw and the fixing body and therefore leads to the bracing rod being unstable relative to the anchor screw.

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SUMMARY OF THE INVENTION

The object of the invention is thus to remedy the drawbacks of prior art implants by proposing an implant for an osteosynthesis device of the spine comprising a bone anchor screw fitted with a ball joint for receiving a bracing rod,
20 such an implant being designed to be put into place quickly and easily, while also being adapted to enable an effective and durable connection to be made between the bracing rod and the bone anchor screw.

To achieve such an object, the implant for an osteosynthesis device, in particular of the spine, comprises:

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- a first assembly comprising:

- a fixing body for a bracing rod, said body being arranged to present a reception housing for receiving an anchor screw head, thereby defining a ball joint between the anchor screw and the fixing body;

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- a positioning ring for interposing between the anchor screw head and the bracing rod;

- and a second assembly comprising a nut type system for fastening the bracing rod to the fixing body.

According to the invention:

- the first assembly has a positioning ring mounted in the fixing body with
35 freedom to move in limited linear displacement and allowing the body and the anchor screw to rotate freely relative to each other in the absence of the bracing rod; and

- the second assembly has a nut type system adapted on being screwed onto the body to bear against the bracing rod and move the positioning ring in linear manner so that on being tightened it clamps the bracing rod between said system and the positioning ring, and also clamps the anchor screw between the positioning ring and the fixing body.

Various other characteristics appear from the following description given with reference to the accompanying drawings which show embodiments and implementations of the invention as non-limiting examples.

10 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view showing a complete implant receiving an intervertebral bracing rod.

Figure 2 is a perspective view of a first assembly forming the implant of the invention.

15 Figure 3 is a section view in elevation of the first assembly, taken substantially on lines III-III of Figure 2.

Figure 4 is a section view in elevation of an implant of the invention taken substantially on lines IV-IV of Figure 1.

20 Figure 5 is a perspective view of a second assembly making up the implant of the invention.

Figure 6 is a section view of a second assembly, taken substantially on lines VI-VI of Figure 5.

BEST MANNER OF PERFORMING THE INVENTION

25 The implant 1 shown in Figure 1 is for an osteosynthesis device (not shown) in particular for the spine. In accordance with the invention the implant 1 is constituted by a first assembly I comprising, in particular, a bone anchor screw 2, and by a second assembly II designed to secure an intervertebral bracing rod 3 relative to the anchor screw 2.

30 As can be seen more clearly in Figures 2 and 3, the first assembly I comprises a fixing body 5 arranged to present a reception housing 6 for receiving the head 7 of the anchor screw 2 which extends beyond the end of a threaded anchor rod 8 of longitudinal axis x . In conventional manner, the head 7 of the anchor screw 2 is generally in the form of a sphere truncated at its summit and provided with a blind hole 9 of polygonal section to enable the anchor screw 2 to be turned by means of a screw-driving tool that is not shown but that is conventional.

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In the example shown, the fixing body 5 has a head 11 constituted in the form of a socket on a longitudinal axis y , with a cavity 12 formed therein centered on the longitudinal axis y . In a preferred embodiment, two diametrically-opposite side branches or walls 13 project from the fixing head 11 so as to define between them a reception channel 14 for receiving the bracing rod 3. The cavity 12 opens out into the channel 14 between the side branches 13, via an orifice 15 formed through the bottom 16 of the cavity 12. The reception channel 14 opens out on either side of the head 5 in a direction that is perpendicular to the diametral plane of symmetry containing the side branches 12. The reception channel 14 is preferably arranged in the top portion of the fixing head 11 so as to have a notch 16 of semicircular profile to enable part of the bracing rod 3 to be received therein, such a rod conventionally being of circular cross-section.

The first assembly I also has a positioning ring 21 for interposing between the head 7 of the anchor screw and the bracing rod 3. This positioning ring 21 is mounted inside the cavity 12 and has a central bore 22 of partly spherical shape opening out via a first transverse face 23 for co-operating with the top portion of the head 7 of the anchor screw. Naturally, the greatest diameter of the central bore 22 is smaller than the diameter of the head 7 of the anchor screw. The positioning ring 21 is capable of limited displacement along the axis of symmetry y of the body 5 between the bottom 16 of the cavity 12 and the head 7 of the anchor screw. In a preferred embodiment, the positioning ring 21 is guided to move with limited linear displacement along the longitudinal axis y . In the example shown, the ring 21 is guided to move in linear displacement by means of a guide peg 24 interposed between the fixing body 5 and the positioning ring 21. For example, the guide peg 24 is engaged in blind bores formed in the bottom 16 of the cavity 12 and a second transverse face 25 of the positioning ring extending facing the bottom 16 of the cavity.

It should be observed that the central bore 22 of the positioning ring 21 opens out via a through opening 27 into the second transverse face 25 so as to communicate with the orifice 15 formed in the head 11, thereby providing access for a screw-driving tool to the blind hole 9 in the anchor screw. The second transverse face 25 of the positioning ring 21 preferably presents a concave surface 28 complementary to the bracing rod 3. This concave surface 28 thus forms a kind of cradle continuing the notch 16 so as to define a portion of the reception channel 14 for receiving the bracing rod 3. It should be observed that the concave face 28 lies automatically in line with the notches 16 for receiving the bracing rod 3 given that the positioning ring 21 is guided in linear displacement along the longitudinal axis y .

As can be seen more clearly in Figure 3, the anchor screw 2 is held assembled to the fixing body 5 by means of a closure cup 29 fixed to the fixing head 11. This closure cup 29 possesses a central bore 30 of part spherical shape complementary to the profile of the bottom portion of the head 7 of the anchor screw. The central bore 30 possesses a maximum diameter which is naturally smaller than the diameter of the head 7 of the anchor screw. In the example shown, the closure cup 29 is fixed to the fixing head 11 by means of a peripheral bead of welding 31. The anchor screw 2 is thus mounted to the fixing body 5 via a ball joint making it possible for the fixing body 5 and the anchor screw 2 to move angularly relative to each other within a cone. The head 7 of the anchor screw 2 thus co-operates with the internal bores 22, 30 respectively of the positioning ring 21 and of the closure cup 29 so that together they define the housing 6 for guiding the head 7 of the anchor screw in rotation.

The way the assembly I is put together stems directly from the description above. The fixing head 11 is designed to receive the positioning ring 21 in the cavity 12, while ensuring that the guide peg 24 is engaged between the positioning ring 21 and the fixing head 11. The internal bore 30 of the closure cup 29 is engaged on the threaded end 8 of the anchor screw 2 and moves up to the head 7. The head 7 of the anchor screw 2 is inserted into the internal bore 22 of the positioning ring 21. The closure cup 29 has the anchor screw 2 passing through it and it is fixed to the fixing head 11 by welding in the example shown. It should be observed that in the absence of the bracing rod 3, the positioning ring 21 is free to move in linear displacement over a limited stroke so as to allow the head 7 of the anchor screw 2 to rotate relative to the fixing body 5.

It should be understood that the anchor screw 2 is assembled to the fixing body 5 prior to being used. Thus, the assembly I is presented in the form of a single unit ready for directly receiving the bracing rod 3 which is fixed to the fixing body 5 by means of the second assembly II which is a nut type fastener. In a preferred embodiment, the fastener assembly II is a nut 33 of the type described in patent application WO 98/41159.

In this preferred embodiment shown more particularly in Figures 4 to 6, the side branches 13 have outside walls 34 inscribed within a circle and threaded to receive the nut 33 which, in conventional manner, has a polygonal outside section to enable it to be held by an appropriate tool. The nut 33 has tapping 35 for screwing onto the threaded walls 34 of the side branches 13.

The nut 33 is fitted with a shoe 36 extending diametrically across the tapping 35 and mounted free to rotate relative to the nut 33 so as to come to bear against the bracing rod 3 in order to hold it in place by being tightened between said shoe 36 and

the positioning ring 21. The width L of the shoe 36 is adapted to leave two gaps 37 on either side, each serving to pass one of the side branches 13 of the fixing body 5. The gaps 37 also make it possible to insert the two pins of a tool (not shown) for taking hold of the nut 33. The pins of the tool can be positioned by engaging them in notches 38 formed in the sides of the shoe 36. In order to enable the pins of the tool to be guided and consequently to enable the shoe 36 to be indexed between the side branches 13 even while it is out of sight, the inside walls of the side branches 13 have respective longitudinal slots 39 extending from the free ends of the branches 13 as far as the fixing head 11. Advantageously, the shoe 36 has an inside transverse surface 40 that is concave and complementary to the top surface of the bracing rod 3.

In an advantageous characteristic shown in Figures 5 and 6, the shoe 36 is snap-fastened to the nut 33. As can be seen in Figures 5 and 6, the nut 33 has a peripheral groove 43 formed at the base of the nut for receiving ribs 44 extending from opposite ends of the shoe 36 and suitable for deforming elastically so as to snap-fasten in the groove 43.

The way the implant 1 of the invention, made up of two assemblies I and II, is used stems directly from the above description.

The assembly I without the assembly II is initially used for implanting the anchor screw 2 in a determined vertebra. Thereafter, the bracing rod 3 is placed so as to be inserted between the side branches 13 of the fixing body 5. Given the freedom for relative rotation between the anchor screw 2 and the fixing body 5, the bracing rod 3 positions itself automatically inside the reception channel 14 of the body 5.

Thereafter, the nut 33 is screwed onto the outside walls 34 of the side branches 13 with the shoe 36 being engaged between the branches 13. Tightening the nut 33 causes the shoe 36 to move so as to come to bear against the bracing rod 3. Continued tightening leads to the positioning ring 21 being subjected to limited linear displacement so as to exert a force on the head 7 of the anchor screw 2. Such tightening of the nut 33 leads to the anchor screw 2 being clamped between the positioning ring 21 and the closure cup 29, and also to the bracing rod 3 being clamped between the shoe 36 and the positioning ring 21. It should be observed that tightening the nut 33 onto the outside walls 34 of the side branches 13 ensures that they cannot splay apart when the shoe 36 applies a thrust force on the bracing rod 3. This assembly makes it possible to obtain large contact area between the shoe 36 and the bracing rod 3, thereby giving rise to effective and long-lasting clamping of the bracing rod 3 relative to the fixing body 5.

CLAIMS

1/ An implant for an osteosynthesis device, in particular for the spine, the implant comprising:

- a first assembly (I) comprising:

5 - a fixing body (5) for a bracing rod (3), said body being arranged to present a reception housing (6) for receiving an anchor screw head (7), thereby defining a ball joint between the anchor screw (2) and the fixing body;

- a positioning ring (21) for interposing between the anchor screw head (7) and the bracing rod (3);

10 - and a second assembly (II) comprising a nut type system (33) for fastening the bracing rod (3) to the fixing body (5),

the implant being characterized in that:

15 - the first assembly (I) has a positioning ring (21) mounted in the fixing body (5) with freedom to move in limited linear displacement and allowing the body and the anchor screw to rotate freely relative to each other in the absence of the bracing rod (3); and

20 - the second assembly (II) has a nut type system (33) adapted on being screwed onto the body to bear against the bracing rod (3) and move the positioning ring (21) in linear manner so that on being tightened it clamps the bracing rod (3) between said system and the positioning ring (21), and also clamps the anchor screw (2) between the positioning ring (21) and the fixing body (5).

2/ An implant according to claim 1, characterized in that:

25 - the fixing body (5) has two side branches (13) defining a channel (14) between them that opens out on either side of the body in order to receive the bracing rod (3), the side branches (13) having outside walls (34) that are threaded; and

30 - the fastening system (II) comprises a nut (33) adapted to be screwed onto the outside threaded walls (34) of the side branches (13), the nut (33) being fitted in its diametral zone with a shoe (36) mounted to rotate freely and designed to come to bear against the bracing rod (3) so that when tightened it clamps said shoe (36) and the positioning ring (21).

35 3/ An implant according to claim 1, characterized in that the positioning ring (21) presents a concave surface (28) complementary to the bracing rod (3) and is guided to slide in such a manner that the concave surface defines a portion of the reception channel (14) for receiving the bracing rod so as to ensure that the bracing rod (3) is

positioned automatically between the side branches (13) and on the positioning ring (21).

5 4/ An implant according to claim 3, characterized in that the positioning ring (21) is guided to move with limited linear displacement relative to the fixing body (5) by means of a guide peg (24) co-operating with a complementary bore.

10 5/ An implant according to claim 2, 3, or 4, characterized in that the positioning ring (21) presents a through opening (27) opening out between the side walls (13) and over the head (7) of the anchor screw in which there is provided a blind hole (9) suitable for receiving a screw-driver tool passing through the opening (27).

6/ An implant according to claim 1, 2, or 4, characterized in that the fixing body (5) comprises:

15 - a fixing head (11) on which there stand the two side branches (13) and in which there is arranged a cavity (12) opening out at one end between the side branches (13) and opening out at its opposite end;

20 - the positioning ring (21) mounted to move with limited displacement inside the cavity (12) with its surface for receiving the bracing rod opening between the two side branches;

- the head (7) of the anchor screw (2) mounted at least in part inside the cavity (12) so that the positioning ring (21) is interposed between said head (7) and the body (5); and

25 - a closure cup (29) fixed on the fixing body (5) on its inside face to close the cavity (12) and having the anchor screw passing therethrough.

7/ An implant according to claim 1 or claim 5, characterized in that the positioning ring (21) and the closure cup (29) present partly-spherical bores (22, 30) so as to define the reception housing (6) for receiving the head (7) of the anchor screw.

30 8/ An implant according to claim 1, characterized in that the nut (33) has a shoe (36) of width adapted to co-operate with the nut to define on either side of the shoe two gaps (37) serving firstly to receive the two pins of a tool for taking hold of the nut, and secondly to pass the side branches (13) of the fixing body in order to enable said shoe (36) to slide between the side branches (13).

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9/ An implant according to claims 2 and 8, characterized in that the fixing body (5) has two slots (39) arranged facing each other in the inside walls of the side branches so that once the bracing rod (3) has been installed they guide the pins of the tool on the fixing body and they enable the shoe (36) to be indexed while out of sight
5 between the side branches (13).

10/ An implant according to claim 9, characterized in that the nut (33) has a shoe (36) with two notches (38) being formed on the side edges thereof, said notches opening out into the gaps (37) and being designed to receive and position pins of the tool.
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11/ An implant according to claim 8, characterized in that the nut (33) has means (43, 44) enabling the shoe to be mounted by snap-fastening, which shoe is free to rotate relative to the nut once it has been mounted.

ABSTRACT

AN IMPLANT FOR AN OSTEOSYNTHESIS DEVICE, IN PARTICULAR FOR THE SPINE

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The invention relates to an implant for an osteosynthesis device, in particular for the spine, the implant comprising a first assembly itself comprising: a fixing body having a housing for receiving the head (7) of an anchor screw in such a manner as to define a ball joint; and a positioning ring (21); and a second assembly itself comprising a nut type system (33). According to the invention: the first assembly (I) has a positioning ring (21) mounted in the fixing body; and the second assembly (II) has a nut type system (33), adapted, when tightened on the body, to bear against the bracing rod (3) and to cause the positioning ring (21) to move in linear displacement.

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Translation of the title and the abstract as they were when originally filed by the Applicant. No account has been taken of any changes that may have been made subsequently by the PCT Authorities acting ex officio, e.g. under PCT Rules 37.2, 38.2, and/or 48.3.

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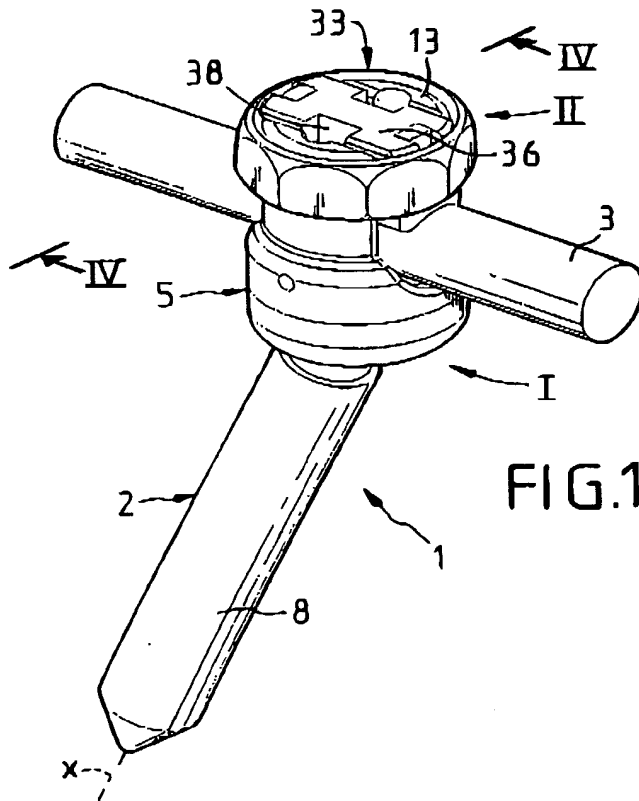


FIG.1

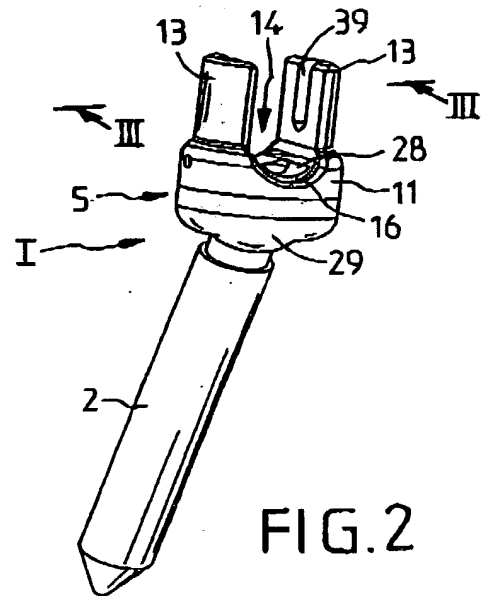


FIG.2

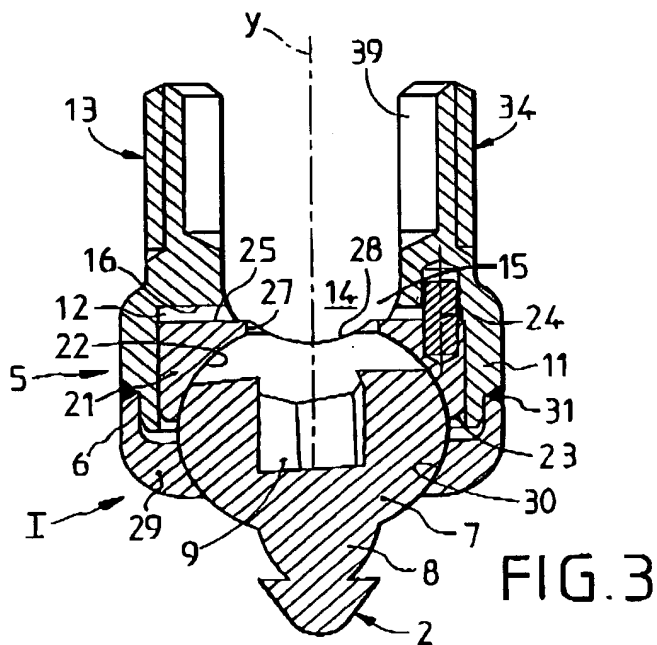


FIG.3

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FIG.4

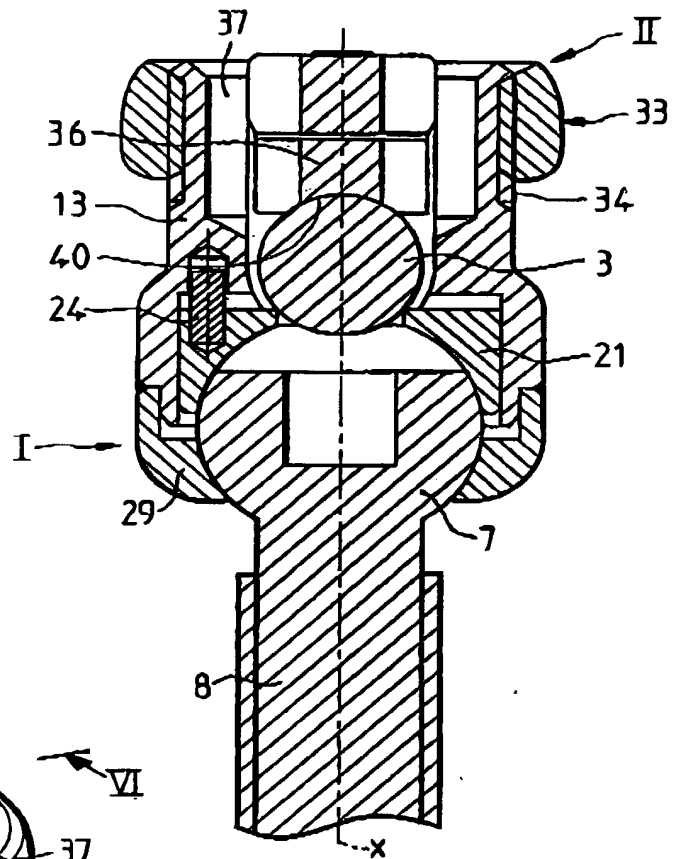


FIG.5

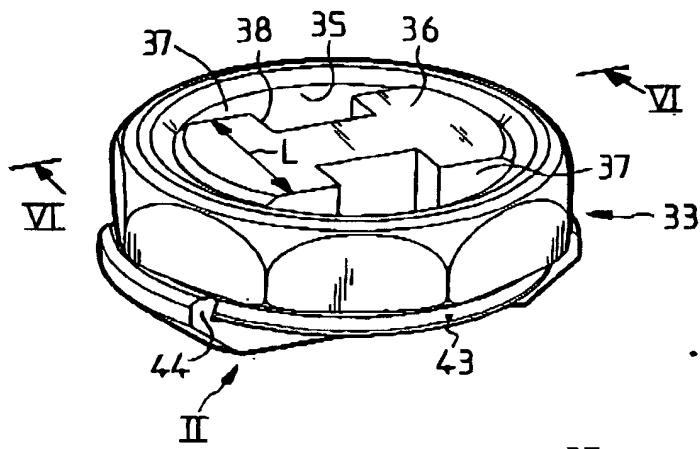
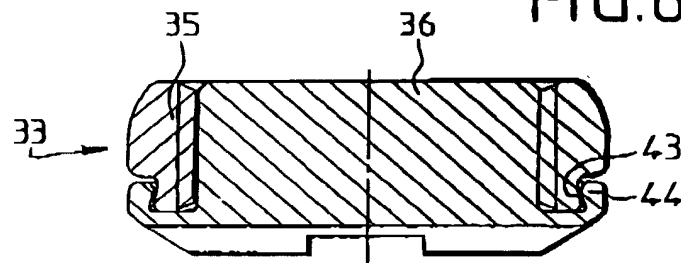


FIG.6



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DATE: November 5, 2002

FROM: Brian W. Hameder/ds

TO: Anita Johnson Fax No. (703) 746-6697
USPTO

RE: Olivier Carli
U.S. Serial No. 10/009,998
Completion of PCT/FROO/01644
Our File: CU-2782

REMARKS:

Dear Ms. Johnson:

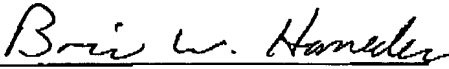
Pursuant to our telephone conversation, attached are the following materials in which the PCT international application has been corrected, in accordance with your request:

1. Transmittal letter (PTO-1390) dated December 14, 2001 (2 pages)
2. Response to Notification of Missing Requirements dated August 22, 2002 (2 pages)
3. Combined Declaration & Power of Attorney (4 pages)
4. Request for Refund of Charges to Deposit Account dated September 4, 2002 (3 pages)

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Should you have any further questions or need additional materials, please let me know.

Very truly yours,


Brian W. Hameder

BWH:ds

21 OCT '02 19:02 BEAU DE LOMENIE LYON

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SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b) or (c))

- ☐ (a) is attached hereto.
- ☒ (b) was filed on DECEMBER 14, 2001 as ☐ Serial No. 10/009 998 or
☐ Express Mail No. (as Serial No. not yet known) _____
and was amended on _____ (if applicable).

Note: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the Declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental Declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

- ☒ (c) was described and claimed in PCT International Application No. PCT/FR00/01644
filed on 14 June 2000 and as amended under PCT Article 19 on _____
(if any).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

(also check the following items, if desired)

- ☐ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
- ☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

Page 3 of 4

21 AOT '02 19:23 BEAU DE LOMENIE LYON

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POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith (*list name and registration number*).

Thomas F. Peterson, 24790; Richard J. Streit, 25765; Donald P. Reynolds, 26220; W. Dennis Drehkoff, 27193; Vangelis Economou, 32341; Brian W. Hameder, 45613; Valerie Neymeyer-Tynkov, 46956; Paul B. West, 18947; Joseph H. Handelman, 26179; Peter D. Galloway 27885; John Richards, 31503; Iain C. Baillie, 24090; Richard P. Berg, 28145

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Note: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

Olivier
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